Remarks

Applicants' Representative acknowledges with gratitude the Examiner's most helpful telephone interview of February 4, 2004. The claims have been amended in light of the same.

Claims 1 through 3 and 5 through 19 and new Claims 20 through 25 are pending in the application.

As noted during the interview, Applicants acknowledge with gratitude the Examiner's indication that Claim 11 will be allowed upon addressing 112 issues and rewriting into independent form. Claim 11 has been amended to recite the step of producing spherical structures and rewritten into independent form. Accordingly, Applicants respectfully request the allowance of amended Claim 11.

Claims 1 through 3 and 5 through 19 have been amended to recite that the food components of the invention are spherical structures. Support for this amendment can be found in the application as found, for example on Page 11, first full paragraph, first sentence.

Claim 1 has been further amended to recite that the claimed spherical structures are encapsulated on all sides by surrounding the core and biologically active substance(s) on all sides with shell-forming substance(s), as discussed during the interview. Support for this amendment can be found in the Application as filed, for example on Page 9, last paragraph, first sentence.

Claim 1 has been further amended to recite that the claimed spherical structures are consumed by humans. Support for this amendment can be found in the Application

as filed, for example on Page 9, first full paragraph, first sentence.

Claims 20 through 25 have been added to complete the record for examination and highlight advantageous embodiments of the invention.

Claim 20 is directed to advantageous encapsulated biologically active structures in which the shell-forming substance(s) form a stable complex with at least one of either the core or the biologically active substance(s). Support for Claim 20 can be found in the Application as filed, for example on Page 8, last paragraph, first sentence in its entirety; Page 10, first full paragraph, first full sentence and Page 13, first full paragraph, third sentence.

Claim 21 is directed to benefical embodiments of such structures, in which the biologically active substance(s) are microorganisms. Support for Claim 21 can be found in the Application as filed, for example on Page 11, first partial paragraph, first full sentence.

Claim 22 is directed to advantageous aspects of such embodiments in which the microorganisms have a cell density of greater than 1 X 10^9 per ml CFU. Support for Claim 22 can be found in the Application as filed, for example on Page 12, first full paragraph, first sentence.

Claim 23 is directed to further advantageous aspects of such embodiments in which the microorganisms are cultured within a fermentation medium and the shell-forming substances include at least one component derived from the fermentation medium. Support for Claim 23 can be found in the Application as filed, for example on

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Page 12, second full paragraph, first sentence.

Claim 24 is directed to further advantageous aspects of such embodiments further including an energy source or growth promoter for the microorganisms. Support for Claim 24 can be found in the Application as filed, for example on Page 16, first full paragraph, last sentence and second full paragraph, second sentence.

Claim 25 is directed to beneficial embodiments in which the shell-forming substance comprises at least one component selected from the group consisting of gum arabic, gelatin, albumin, pectin, maltodextrin, and carboxymethyl cellulose. Support for Claim 25 can be found in the Application as filed, for example on Page 14, last paragraph through Page 18, first full paragraph.

Section 112 Rejection

Claims 1 through 3 and 5 through 19 stand rejected under 35 USC § 112 over the phrase "spherical device". Applicants respectfully submit the term "spherical device" is fully supported within the application as filed, and that the subject matter of a claim need not be described literally in order for the disclosure to satisfy the description requirement. The specification as filed conveys with reasonable clarity to one skilled in the art that, as of the filing date sought, applicant was in possession of the claimed spherical devices. However, solely to advance prosecution of the case, the claims have been amended with traverse to recite "spherical structure" in lieu of "spherical device." Support for this amendment can be found in the application as found, for example on Page 11, first full paragraph, first sentence. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claim 11 stands rejected under 35 USC § 112 as being incomplete for omitting essential elements. Claim 11 has been amended to recite the formation of spherical structures. Accordingly, Applicants respectfully request withdrawal of this rejection.

The Claimed Invention is Patentable in Light of the Art of Record

Claims 1 through 3 and 5 through 10 have been rejected under 35 U.S.C. § 103(a) over United States Patent No. 5,429,832 to Ueda et al. ("Ueda"). Claims 1, 2, 6, 8 through 10 and 12 through 19 stand rejected over United States Patent No. 6,120,811 to Ghani ("Ghani") in view of Ueda.

It may be useful to consider the invention as recited in the claims before addressing the merits of the rejection. The claims recite multifunctional encapsulated biologically active spherical structures consisting of a core that is surrounded by at least one biologically active substance. The core and the biologically active substance(s) are further surrounded on all sides by one or more shell-forming substance(s). The core includes at least one dietary fiber. The shell-forming substance(s) are advantageously selected from the group consisting of monosaccharides, disaccharides, polysaccharides, emulsifiers, peptides, proteins and prebiotic substances.

The oral delivery of biologically active substances to desirable sites within the lower gastrointestinal tract is highly problematic. Biologically active substances are typically decomposed or destroyed by conditions encountered within the upper gastrointestinal tract, e.g. highly acidic stomach acids and the like. The delivery of living medicinal agents to the intestines is especially difficult. It has been long known in the art that the survival rates of microorganisms added directly to food are too low to

develop nutritional effects.

Surprisingly, Applicants have found structures capable of delivering effective amounts of biologically active substances to target sites within the lower gastrointestinal tracts. More particularly, Applicants have found that encapsulated structures that include both dietary fiber and biologically active substances encapsulated within a protective outer shell may be used to deliver active substances to the intestines.

In addition to their numerous health benefits, Applicants have found that the recited dietary fibers provide support for and stability to the biologically active substances during delivery. Applicants have further determined that the claimed structures allow dietary fiber to be administered without the adverse sensory perceptions, e.g. scratchy off-taste, normally associated with dietary fiber.

In advantageous embodiments, the shell materials form complexes with at least one of either the biolocially active substances or the dietary fiber to provide further stability for the biologically active substance, as recited in Claims 3 and 20. In highly advantageous aspects of the invention, the biologically active substances are microorganisms, as recited in Claims 21 – 25.

The art of record does not teach or suggest the claimed invention. In contrast to the recited structures for human ingestion, Ueda is directed to feed additives for ruminants. The feed additives are in the form of microgranules. The microgranules are said to be stable in the rumen of ruminants. (Col. 1, lines 7 – 11). Ueda's microgranules are formed from a biologically active substance coated with a composition that includes a specified combination of a saturated fatty acid, chitosan, and an emulsifier. (Col. 2, lines 36 – 50). Ueda provides an extensive list of suitable

biologically active substances. (Col. 4, lines 10 – 40). Microorganisms are noticeably absent from Ueda's list. Ueda notes instead that microorganisms are known to decompose biologically active substances during ruminant digestion. (Col. 1, lines 21). Ueda generally produces his microgranules using fluidized-bed coating and the like. (Col. 6, lines 8 – 10). Ueda's microgranules range in size from 0.5 to 5 mm. (Col. 6, lines 15 – 17). If the particles are smaller than 0.5 mm, "coating the particles by an ordinary method" becomes difficult. (Col. 6, lines 13 – 15).

There would have been no motivation to have looked to Ueda. The digestive systems of ruminants are vastly different from human digestive systems. However, even if Applicants had looked to Ueda (which they did not), the claimed invention would not have resulted.

Amongst other distinguishing features, Ueda does not teach or suggest the recited structures intended for human ingestion. Ueda further does not teach or suggest such structures incorporating the recited dietary fiber.

In addition, Ueda, directed to microgranules, does not teach or suggest the recited encapsulated structures, in which the core and biologically active substance(s) are encapsulated on all sides by one or more shell-forming substance(s), as discussed during the interview. Applicants respectfully submit that Ueda's microgranules do not exhbit the same physical structure of the claimed invention (encapsulation), because Ueda's microgranules are formed using completely different process. The varying methods of production between Ueda and the claimed invention do impart altogether different physical structures to the resulting materials, i.e. encapsulated structures versus microgranules.

More particularly, in contrast to the opinion urged in the Office Action, the term "encapsulated" is understood by those skilled in the art to mean a device having an inner core that is disposed within a countinous outer shell. The Examiner's attention is respectfully directed to the enclosed Inventor's Declaration by Dr. Kunz, named inventor, further discussing the art recognized definition of "encapsulation," attached as Exhibit I. Dr. Kunz's declaration provides numerous definitions which reflect the continuous nature of the outer shell of encapsulated structures, including:

"Microencapsulation is a technique whereby liquid droplets, particles, or gas bubbles of a "core-meterial" are entrapped in a continuous film ... " Zilberboim, R., Kopelmann, I.J., Talmon, Y., *Microencapsulation by a Dehydrating Liquid: Retention of Paprika Oleoresin and Aromatic Esters*, Journal of Food Science 1987, 51(5), S. 1301 – 1306.

Hence the claimed invention clearly provides core material around the entire circumference of the spherical structure, in contrast to Ueda.

Ueda further does not teach or suggest shell-forming substance(s) forming stable complexes with at least one of either the core or the biologically active substance(s), as recited in Claim 20. In contrast to the claimed invention, Ueda is merely directed to coated microgranules.

Ueda also does not teach or suggest embodiments in which the biologically active substance(s) are microorganisms, as recited in Claim 21. In fact, Ueda teaches away from such embodiments, by noting that microorganisms actually destroy biologically active materials. As Ueda does not teach or suggest microorganisms, he certainly does not teach or suggest microorganisms having a cell density of greater than 1×10^9 per ml CFU, as recited in Claim 22. Similarly, Ueda most certainly does

not teach or suggest aspects of the invention in which the shell-forming substances include at least one component derived from the microorganism fermentation medium, as recited in Claim 23. Nor does Ueda teach or suggest advantageous embodiments further including an energy source or growth promoter for the microorganisms, as recited in Claim 24.

Ueda, directed to a very particular shell composition to be used in conjunction with the digestive system of ruminants, also does not teach or suggest the beneficial embodiments in which the shell-forming substance comprises at least one component selected from the group consisting of gum arabic, gelatin, albumin, pectin, maltodextrin, and carboxymethyl cellulose, as recited in Claim 25.

Based on the foregoing, Applicants respectfully submit that the claimed invention is patentable in light of Ueda, considered either alone or in combination with the art of record.

Ghani is generally directed to low dusting microgranules which contain enzymes. The microgranules are primarily intended for use in food, such as baked goods. (Col. 1, lines 38 - 41). Rather than be ingested, Ghani's microgranule are designed to dissolve upon combination with the remainder of the food ingredients. (Col. 2, lines 48 – 52). Ghani emphasizes the ready dissolution of his microgranules several times within his specification. Ghani's microgranules are designed to "disperse quickly" within an aqueous environment to provide "an even distribution" of enzyme within the remaining food ingredients and that the microgranules should "disintegrate rapidly" in an aqueous environment. (Col. 1, lines 42- 45 and lines 48 - 52). In fact, Ghani prefers the microgranules to dissolve in "less than or equal to one minute" upon encountering an aqueous environment. (Col. 5, lines 33 – 35). An exemplary aqueous environment

noted by Ghani is "the small amount of water used during the dough making process." (Col. 2, lines 50 – 52). Hence the microgranules of Ghani dissolve prior to baking.

Ghani's microgranules generally include a carrier, an enzyme, a binder, and a water soluble coating. (Col. 1, lines 59 – 65). Suitable carriers include soy flour and the like. (Col. 2, lines 30 – 32). Suitable binders include starches, corn syrup and the like. (Col. 2, lines 45 – 48). The binder initially binds the enzyme to the carrier material and later aids in breaking down the microgranule upon combination with the remaining ingredients. (Col. 2, lines 35 – 38 and lines 48 – 52). Suitable water soluble coatings include low viscosity algins and the like. (Col. 2, lines 53 – 55). Ghani's microgranules may range up to 400 microns in size. (Col. 1, line 48). Similar to Ueda, Ghani's microgranules are formed using agglomeration, preferably in a fluidized-bed process. (Col. 1, lines 53 – 56 and Col. 3, lines 61 - 66).

Ghani also does not teach or suggest the claimed invention, considered either alone or in combination with Ueda. Amongst other distinguishing features, Ghani does not teach or suggest structures intended for ingestion. In fact, Ghani strongly teaches away from such structures by requiring his microgranules to disintegrate prior to ingestion. Ghani further does not teach or suggest such structures incorporating the recited dietary fiber.

Ghani, also directed to microgranules, does not teach or suggest the recited encapsulated structures, in which the core and biologically active substance(s) are surrounded on all sides by one or more shell-forming substance(s), as further noted during the interview. As was the case with Ueda, Applicants likewise respectfully submit that Ghani's microgranules do not exhbit the same physical structure of the claimed invention because Ghani's microgranules are formed using completely different

processes.

Ghani further does not teach or suggest shell-forming substance(s) forming stable complexes with at least one of either the core or the biologically active substance(s), as recited in Claim 20. In fact, Ghani teaches away from stable complexes by requiring his microgranules to disintegrate rapidly upon encountering an aqueous environment.

Ghani further does not teach or suggest such embodiments further incorporating microorganisms, as recited in Claim 21. As Ghani does not teach or suggest such embodiments, he certainly does not teach or suggest microorganisms having a cell density of greater than 1 X 10^9 per ml CFU, as recited in Claim 22. Similarly, Ghani most certainly does not teach or suggest aspects of the invention in which the shell-forming substances include at least one component derived from the microorganism fermentation medium, as recited in Claim 23. Nor does Ghani teach or suggest advantageous embodiments in which microrganisms are further provided with an energy source or growth promoter, as recited in Claim 24.

Ghani, directed to a very particular shell composition designed to provide rapid dissolution within aqueous environments, also does not teach or suggest the beneficial embodiments in which the shell-forming substance comprises at least one component selected from the group consisting of gum arabic, gelatin, albumin, pectin, maltodextrin, and carboxymethyl cellulose, as recited in Claim 25.

There would have been no motivation to have even looked to Ghani, much less combine Ghani and Ueda. Ghani is directed to microgranules that dissolve prior to consumption. Ueda is directed to microgranules for ruminants. Consequently, even if

combined (which Applicants submit should not be done), the recited encapsulated biologically active structures for human ingestion that include at least one dietary fiber and at least one biologically active substance that are encapsulated on all sides by one or more shell-forming substance(s) would not have resulted. Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of Ghani, considered either alone or in combination with Ueda.

Conclusion

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 3 and 5 through 19 (amended pursuant to the telephone interview of February 4, 2004) and new Claims 20 through 25 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional fees are necessary to allow consideration of this paper, the fees are hereby authorized to be charged to Deposit Account No. 50-2193.

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being transmitted to facsimile number (703) 872-9306 at the United States Patent and Trademark Office on March 3, 2004.

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